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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,472	07/02/2003	Frederick M. Ausubel	00786/254004	5312

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EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,472	AUSUBEL ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *19 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4 are pending.

2. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from Table 1 on pg 31, and from pg 40, line 8.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying plant disease resistance genes comprising introducing a candidate gene into a plant via biolistic transformation and assaying the plant for

disease resistance, does not reasonably provide enablement for a method of identifying plant disease resistance genes comprising introducing candidate genes from cDNA libraries into any plant tissue via biolistic transformation and assaying the plant tissue for disease resistance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of identifying plant disease resistance genes comprising introducing candidate genes into plant tissue via biolistic transformation and assaying the plant tissue for disease resistance.

The instant specification, however, only provides guidance for the cloning of the RPS2 gene from Arabidopsis (pg 24-38), general guidance for isolation of related genes form other plants (pg 38-47); a biolistic transient expression assay that requires the plant cells have a mutant resistance gene (pg 47-52); and general guidance for expressing RPS2 in plants (pg 54-62).

The instant specification fails to provide guidance for a method of identifying plant disease resistance genes comprising introducing candidate genes into plant tissue via biolistic transformation and assaying the plant tissue for disease resistance.

Keen et al (1993, Biotechnology in Plant Disease Control (Chet, ed.), pg 65-88) states that intact plants must be used in this method; thus, any plant tissue alone cannot be used. Applicant's method described on pg 47-52 requires that the plant tissue have a mutant resistance gene.

Keen et al also state that use of cDNA libraries in the method requires high quality genomic and cDNA expression libraries, which at the time of publication was considered a major technical obstacle to the method.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for identifying plant disease resistance genes comprising introducing candidate genes into plant tissue via biolistic transformation and assaying the plant tissue for disease resistance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Keen et al (1993, Biotechnology in Plant Disease Control (Chet, ed.), pg 65-88).

Keen et al disclose a method of identifying plant disease resistance genes comprising introducing candidate genes from cDNA libraries into a plant via biolistic transformation and assaying the plant for disease resistance (pg 79, paragraph 4, to pg 82, paragraph 1). The plant would comprise leaves, roots and stems and at certain points in its life would comprise flowers and fruit. The assayed disease resistance response is the hypersensitive response (pg 80, paragraph 1; pg 81, paragraph 2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-2 rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes et al (1993, Plant Science 89:43-53) in view of Daniell et al (US Patent 5,693,507, filed at least January 1991).

The claims are drawn to a method of identifying plant disease resistance genes comprising introducing a candidate genes into a plant via biolistic transformation and assaying the plant for disease resistance.

Jaynes et al disclose a method of identifying genes that confer disease resistance on a plant, wherein the method comprises introducing a candidate gene encoding cecropin B into a tobacco plant via Agrobacterium transformation and assaying the plant for disease resistance (pg pg 48-50). Jaynes et al do not disclose use of biolistic transformation in the method.

Daniell et al teach biolistic transformation of tobacco (column 11, lines 55-65)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of identifying genes that confer disease resistance as taught by Jaynes et al, to introduce the gene via biolistic transformation as described in Daniell et al. One

of ordinary skill in the art would have been motivated to do so because selection of one transformation over another is an obvious design choice.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

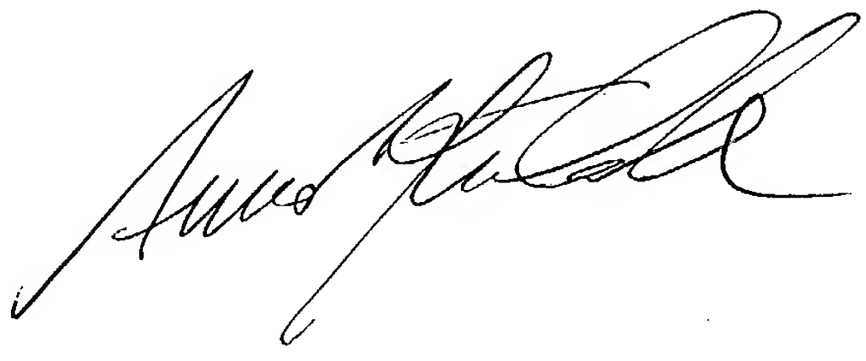
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
December 15, 2004



ANNE KUBELIK
PATENT EXAMINER